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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,206	07/29/2003	Kei Roger Aoki	17328CON4	1996

7590 07/16/2007

Stephen Donovan
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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
07/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,206

Applicant(s)

AOKI ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,9,12,13,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9,12,13,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> |

Continuation of Attachment(s) 6). Other: "trigeminal neuralgia" definition.

DETAILED ACTION

Status of the Claims

1. Claims 1, 4, 5, 9, 12, 13, 31 and 32 are pending.

Applicants' amendment filed May 1, 2007 is acknowledged, and applicants' response has been fully considered. Claims 1, 12, 13 and 31 have been amended. Thus, claims 1, 4, 5, 9, 12, 13, 31 and 32 are examined.

Withdrawn Claim Objections

2. The previous objection of claims 1, 12 and 31 is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 3 in the amendment filed May 1, 2007.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1, 4, 5, 9, 12, 13, 31 and 32 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicant's response at pages 5-7 in the amendment filed May 1, 2007.
4. The previous rejection of claim 13 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicant's response at page 4 in the amendment filed May 1, 2007.

New Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 4, 5, 9, 12, 13, 31 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U. S. Patent 6,869,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 4, 5, 9, 12, 13, 31 and 32 in the instant application disclose a method for treating a face pain, the method comprising peripheral administration of a botulinum toxin to the face of a mammal, wherein the face pain is not due to headache, and the face pain is not associated with a muscle disorder; and the specification indicates various neuralgias include herpetic neuralgia, trigeminal neuralgia and other neuralgias (page 5, lines 11-14). It is known that trigeminal neuralgia is a facial pain typically near the nose, lips, eyes or ears (see the definition attached). This is obvious variation in view of claims 1-3 of the patent which disclose a method for alleviating neuralgia, comprising peripheral administration of a therapeutically effective amount of a botulinum toxin to a human patient, wherein the pain is not associated with a headache; and the specification indicates various neuralgias include herpetic neuralgia, trigeminal neuralgia and other neuralgias (column 3, lines 31-36). Both sets of claims cite a method of treating a face pain (e.g., trigeminal neuralgia) or neuralgia, comprising peripheral administration of a botulinum toxin to a mammal. Thus, claims 1, 4, 5, 9, 12, 13, 31 and 32 in present application and claims 1-3 in the patent are obvious variations of a method of treating a face pain (e.g., trigeminal neuralgia) or neuralgia, comprising peripheral administration of a botulinum toxin to a mammal.

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Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

July10, 2007

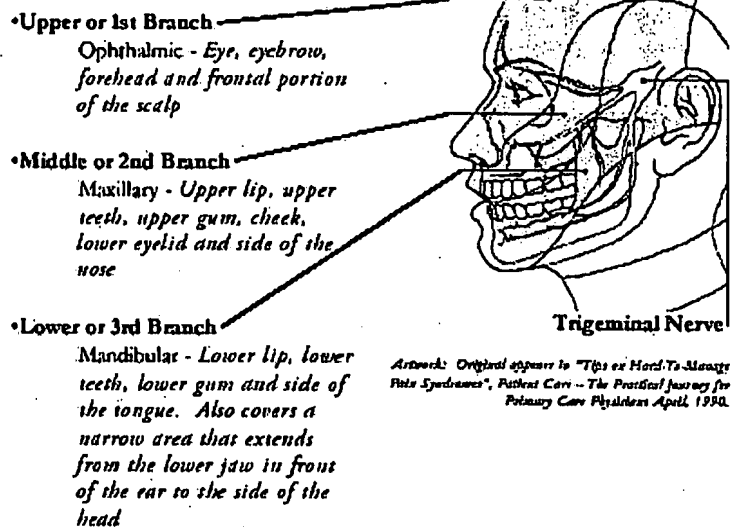
WHAT IS TRIGEMINAL NEURALGIA?

Glossary

TN (Trigeminal Neuralgia) is a pain that is described as among the most acute known to mankind. TN produces excruciating, lightning strikes of facial pain, typically near the nose, lips, eyes or ears.

TN (Trigeminal Neuralgia / tic douloureux) is a disorder of the fifth cranial (trigeminal) nerve that causes episodes of intense, stabbing, electric shock-like pain in the areas of the face where the branches of the nerve are distributed - lips, eyes, nose, scalp,

forehead, upper jaw, and lower jaw. By many, it's called the "suicide disease". A less common form of the disorder called "Atypical Trigeminal Neuralgia" may cause less intense, constant, dull burning or aching pain, sometimes with occasional electric shock-like stabs. Both forms of the disorder most often affect one side of the face, but some patients experience pain at different times on both sides. Onset of symptoms occurs most often after age 50, but cases are known in children and even infants. Something as simple and routine as brushing the teeth, putting on makeup or even a slight breeze can trigger an attack, resulting in sheer agony for the individual. Trigeminal neuralgia (TN) is not fatal, but it is universally considered to be the most painful affliction known to medical practice. Initial treatment of TN is usually by means of anti-convulsant drugs, such as Tegretol or Neurontin. Some anti-depressant drugs also have significant pain relieving effects. Should medication be ineffective or if it produces undesirable side effects, neurosurgical procedures are available to relieve pressure on the nerve or to reduce nerve sensitivity. Some patients report having reduced or relieved pain by means of alternative medical therapies such as acupuncture, chiropractic adjustment, self-hypnosis or meditation.



TREATMENTS

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